Senate Finance, Ways & Means Committee Amendment No. 1

Amendment No. 2 to HB1410

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Clerk _____
Comm. Amdt. _____
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Fitzhugh
Signature of Sponsor

AMEND Senate Bill No. 1360* House Bill No. 1410

by deleting all language after the enacting clause and by substituting instead the following language:

SECTION 1. Tennessee Code Annotated, Title 39 Chapter 17, is amended by deleting Section 421 in its entirety and substituting instead the following language.

§ **39-17-421.** (a) Except as provided in Title 53, Chapter 10, Part 2, it shall be unlawful for any pharmacist, or any pharmacy technician or any pharmacy intern under the supervision of a pharmacist who dispenses prescriptions, drugs, and medicines to substitute any drug or device different from the one ordered, or deviate in any manner from the requirements of an order or prescription without the approval of the prescriber as defined in 63-10-204.

(b) A violation of this section is a Class C misdemeanor.

SECTION 2. Tennessee Code Annotated, Title 53, Chapter 10, is amended by deleting Part 2 in its entirety and by substituting instead Sections 3 through 11 of this act as new Part 2.

SECTION 3. This act shall be known and may be cited as the "Tennessee Affordable Drug Act of 2005."

SECTION 4. The general assembly declares it to be the public policy that in order to lower the cost of prescription drugs to its citizens, pharmacists may substitute less costly generic drugs or drug products for higher priced brand name or trade name drugs or drug products.

SECTION 5. As used in this part unless the context otherwise requires:

(1) "Brand name" means the registered trademark name of a drug or drug product given by its manufacturer, labeler or distributor;

(2) “Finished dosage form” means that form of a drug which is, or is intended to be, dispensed or administered to a patient and requires no further manufacturing or processing other than packaging, reconstitution or labeling;

(3) “Generic equivalent” means a drug product which has the same established name, active ingredient(s), strength or concentration, dosage form, and route of administration and which is formulated to contain the same amount of active ingredient(s) in the same dosage form and to meet the same compendial or other applicable standards (i.e. strength, quality, purity, and identity), but which may differ in characteristics, such as shape, scoring, configuration, packaging, excipients (including colors, flavors, preservatives), and expiration time;

(4) “Prescriber” means an individual authorized by law to prescribe drugs;

SECTION 6.

a) The prescriber shall allow for substitution with a generic equivalent of a brand name drug or drug product under all circumstances unless as provided in this subsection.

1) The prescriber determines the medical necessity of a brand name drug or drug product due to:

a. Adverse reaction previously experienced by the patient to a generic equivalent,

b. A generic equivalent has previously been demonstrated as ineffective for the patient, or

c. Any other clinically based prescriber determined need.

2) A generic equivalent is not available.

b) If the prescriber determines a brand name drug or drug product is medically necessary for a patient, the prescriber shall, in the prescribers own handwriting, place the instruction showing intent upon the prescription at the time it is prepared and issued. For the purposes of this subsection, instruction showing intent may include, but not be limited to, the following language:

1) “Brand name medically necessary”, “dispense as written”, “medically necessary”, “brand name”, “no generic”; or,

2) Any abbreviation of the language in the subsection above; or,

3) Any other prescriber handwritten notation, such as circling a preprinted dispense as written on the prescription order, that clearly conveys the intent that a brand name is necessary for this patient.

c) If the prescriber determines a brand name drug or drug product is medically necessary for a patient and that prescription order is issued verbally, the prescriber shall alert the pharmacist that use of the brand name drug or drug product is medically necessary for the patient.

d) If the prescriber determines the brand name drug or drug product is medically necessary for a patient and that prescription is sent to the pharmacist through electronic technology or through facsimile, the prescriber shall place the proper instruction on the prescription at the time it is prepared electronically.

e) Nothing in this section shall be construed to prevent a prescriber from informing a patient of the prescriber’s professional opinion as to the capabilities, effectiveness and acceptability of any drug.

SECTION 7.

a) When a pharmacist receives a written, verbal, electronic or facsimile prescription order and the prescriber has not noted medical necessity of the brand name prescribed as required in Section 6, the pharmacist shall dispense the least expensive generic equivalent in stock, or a generic equivalent covered under the patient’s drug plan, except as provided below in Section 7 (c) and Section 7 (e).

b) A pharmacist shall make a reasonable attempt to notify a prescriber if a generic equivalent has become available since the last dispensing of a prescription and if authorized by the prescriber the pharmacist shall dispense the least expensive generic equivalent in stock, or a generic equivalent covered under the patient’s drug plan.

c) If a pharmacist has reason to believe that the brand name drug or drug product is less expensive to the patient or patient's drug plan than the generic equivalent, the pharmacist shall fill the prescription with the brand name drug or drug product.

d) When a pharmacist receives a written, verbal, electronic, or facsimile prescription order and the prescriber has not noted medical necessity of the brand name as required in Section 6, the pharmacist shall dispense the appropriate drug pursuant to subsection 7 a), unless the patient is individually paying the entire cost of the prescription at the time of dispensing and objects to any substitution.

SECTION 8. A pharmacist who selects a generic equivalent for substitution pursuant to Sections 6 has the same responsibility for the selected drug as such pharmacist would in dispensing a prescription for the drug prescribed by its trade or brand name.

SECTION 9.

a) The manufacturer, packager, or distributor of any human use legend drug sold, delivered or offered for sale in the state of Tennessee must have printed on the label of the immediate container of the drug the name and address of the manufacturer, packager, or distributor of the finished dosage form of the drug.

b) The pharmacist shall notify the patient of the substitution with a generic equivalent by noting the substitution on the prescription label.

c) This provisions of this section shall not apply to prescriptions dispensed for inpatients of a hospital, a nursing home or an assisted care living facility as defined in §68-11-201.

SECTION 10. In making substitutions as allowed by this part, the pharmacist may use drugs and drug products manufactured within the territorial limits of any one of the states of the United States or any other country if such products have been approved by the federal food and drug administration.

SECTION 11. Nothing in this act shall be construed as authorizing any person or entity to interfere with a prescriber's obligation to exercise independent medical judgment in rendering healthcare services to patients.

SECTION 12. If any provision of this act or the application thereof to any person or circumstance is held invalid, then such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to that end the provisions of this act are declared to be severable.

SECTION 13. This act shall take effect upon becoming a law, the public welfare requiring it.